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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/746,360	11/08/1996	TED CHRISTOPHER	9872	7522

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EXAMINER
JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
3737	

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PR

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER
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Commissioner of Patents and Trademarks

A decision has been rendered in the Public Use proceeding in this application and is forwarded herewith.

Francis J. Jaworski
Primary Examiner

In re Application of Ted Christopher :
Application Number 08/746,360 : Public Use Proceeding
Filed: November 8, 1996 :
Attorney Docket No. 9872 :

SUMMARY DECISION

A finding has been made in favor of the applicant that no public use of the claimed invention occurred.

BACKGROUND

(1) The Christopher application U.S. 08/746,360 is directed to reduction to practice of finite amplitude distortion-based pulse-echo ultrasound imaging of a sample or media, especially of inhomogenous media for which conventional B-mode imaging at a fundamental transmit and receive frequency suffers from significant defocussing lateral resolution and contrast losses due to the inhomogeneous nature of the sample or media. The inhomogenously constituted sample or media may be native human tissue and the imaging is then native tissue harmonic-based ultrasound pulse echo imaging.

(2) Harmonic echoes arise in conventional B-mode imaging where they create artifact, particularly at higher transmit powers. Harmonic echoes also arise due to bubble resonance effects in contrast agent-based imaging when such contrast agent is present, which may be in the bloodstream or by perfusion into the capillaries where the agent then harmonically highlights blood-laden tissue as an indication of perfusion. Whereas the harmonic contrast agent effect is target-(i.e. bubble-site) generated, the native tissue harmonic effect arises due to a cumulation of amplitude-based distortion as the ensonating pulse wave passes through tissue and is due to the advancing of axial wave velocity of the compression side of the ultrasound wave pulse along the beamline versus delaying of the wave velocity on the rarefaction side of the pulse (this wave being an elastic or physically propagating wave). Where blood/ perfused-tissue contrast agent harmonic effects and native tissue harmonic effects are both present such as in ultrasound contrast agent studies, under a typical scan the tissue harmonic effect would be about 20Db lower than the contrast agent effect. Additionally, the harmonic effect is

expressed to a greater extent at shallower depths, peaking at approximately 90% of focal distance and undergoing greater frequency-dependent attenuation with respect to the fundamental thereafter, see application Fig. 4A (6 cm focus). Higher transmit power improves the harmonic:fundamental transmit ratio (application Fig. 8) and therefore acts to optimize system sensitivity to the tissue harmonic.

(3) While the Christopher application acknowledges ultrasound contrast agent-based harmonic imaging in general terms (page 18 lines 1 - 9), this is in general terms. Christopher neither directly entertains contrast agent imaging nor does it therefore entertain separating the contrast agent and tissue harmonic effect. It does address separation of the fundamental and the harmonic by virtue of receive bandpass filtering of the composite fundamental plus harmonic, or in the alternative by two-pulse subtraction at differing transmit power levels alone or together with high-pass filtering (p. 34) to take advantage of the Fig. 8 power sensitivity relationship, see specification page 2 line 23 - page 3 line 5 and pages 6-7 bridging and 7-8 bridging.
While these different techniques may be used to separate and accentuate the (second) harmonic, they do not address the loss of sensitivity absent a broadband transducer, since the receive bandwidth of the transducer must be doubled to capture the second harmonic at a high signal-to-noise ratio. How much harmonic content appears in the conventional B-mode system for example would relate to transducer bandwidth. Christopher acknowledges the sensitivity loss and proposes a second receiver (understood to mean a second transducer and/or receiver) for the harmonic reception band, page 18 lines 6 - 9.

(4) The Christopher application is largely directed to graphed transmission characterizations of ultrasound propagating beam behavior such as side-lobe levels using a large (3 cm) focussed single transducer, and in association with in vitro tissue specimen slices including layered cadaver (?) specimens (p. 25) supported on a specimen platform. However an imaging system is disclosed in Fig. 1 and direct enactment of phased array scan imaging is recognized, see also page 9. The specification is replete with reference to in-vivo medical imaging. The claims language is as set forth in the admitted Rule 116 amendment filed June 18, 1998.

DECISION REASONING

(5) The claims, when read in light of the disclosure (such as characterized above) describe the invention, and it is towards the *claimed invention* that the suspect public use must be at bar. Both the apparatus and method claims in essence are directed to pulse echo ultrasound imaging '*principally* of *one of*' the second or higher order non-linear distortion harmonic of a sample ('sample' understood to include in vivo human tissue). Therefore 'apparatus and method for ultrasound imaging of predominantly/chiefly/mainly one native tissue harmonic'

(6) Public use would include direct verbal teaching or other teaching (audiotape, brochure) of the invention and/or the Acuson-provided videos, video being here on modality of record of an event set being weighed in toto for public use bar. And if the system in use directly embodied the method and apparatus then it the public need not have understood it (for example the improvement changes might remain hidden within the scanning system) for public use to have occurred.

(7) In the evidentiary declarations, for example the second declaration of Paul Chandler, this declaration states that a wideband transducer was procured for the 5.0 MHz harmonic imaging mode adaptation such that transmit at 2.5Mhz, receive at 5.0 MHz occurred, it does not say that any filtering (bandpass or highpass) is occurring, nor is it embracing of switched transducer reception (?) or of switched resonance thickness transducer modes (?) to effect wideband capability, that is, selectivity effected essentially at the transducer(s) alone or together with PAL-implemented operation logic. There is nothing to pre-suppose or verify that the system was designed other than to render a contrast agent image such that in the absence of contrast agent the system provides an image principally/chiefly/mainly of a native tissue harmonic component.

(8) In the Christopher application, one must remember the paragraph (3) characterization supra, namely that high pass filtering and/or two-pulse subtraction imaging or a separate switched receive device together with operation near the maximum permissible power (or else combination with a filter) must be had in order to obtain a large isolated second harmonic, ergo approaching an image principally/chiefly/predominantly of that single

extracted harmonic.

(9) The Chandler description is of one avowedly for contrast agent imaging and for whom the second order tissue harmonic is not of concern (recall the intrinsic 20dB contrast agent advantage stated in para (2) supra. In other words, the 1122 or modified Acuson contrast agent scanner is one in which in its specialized use for contrast agent studies, a 20dB advantage is intrinsically had over native finite amplitude distortion effects simply by being generically tailored to accept the second harmonic, a 20dB sensitivity result as sought by Christopher in relation to the fundamental (since no contrast agent is contemplated) on the other hand requiring one or more of the aforementioned filter/2-pulse/power-maxing and definitely at least one of the former two if power be below 2 W/cm-sqd RMS (Figs. 8-9 and text). Under this logic, it does not necessarily follow that the exhibited device was capable of forming an image *principally* of *one* isolated harmonic of native tissue finite amplitude distortion origin.

There is no revelation in any of the testimony material of the petitioner that tissue harmonic imaging was contemplated as an image mode or that any system adaptation was effected soas to image principally/chiefly/predominantly/mainly a native tissue harmonic, or that any tutorial material regarding tissue harmonic imaging was provided to the public evidencing that the system was capable of such imaging or was in fact so used.

(10) The Baker affidavit points out that enhanced edge definition alleged by petitioner is temporally associated with the leading edge of the contrast bolus arrival (Baker paras 20 - 23). In effect, the Examiner is independently adopting a reasoning analogous to paragraphs 27 and 30 of the Baker evidentiary declaration and the Unger declaration regarding lack of sufficient or sufficiently described scanner adaptations and the need for amplitude or frequency selectivity beyond that which the 1122 device as disclosed used.

(11) Since the Petitioner's Evidentiary Declarations fail to establish public

use of the claimed invention as characterized in the italicized portion above, issues regarding credentialing of the affiants, continuity of possession or chain of derivation or manner of alteration in association with the videotapes and/or evidence regarding presentation at the ACC conference are then secondary and do not persuasively weigh against the fundamental decision basis.

(12) All prior art submissions including those of the Petitioner whose contents were not considered will be considered forthwith, since an Examiner cannot knowingly omit consideration of prior art which may be relevant against the language of the claims. This case now reverts to back to an after-final status, and the Examiner will consider the Petitioner's prior art. The additional claims amendment filed December 20, 1999 has not been entered as a matter of right, nor was it filed under Rule 116, however since the Examiner is charged with reviewing the Petitioner's art submissions and since such art did not arrive belatedly due to actions by Applicant, no petition or fee is necessary for such consideration. If this art affects the patentability of any claim, then the Final Rejection will be withdrawn in favor of its application.

Accordingly, a decision has been made that no public use of the claimed invention occurred in the context of events described by the Petitioner.

Francis J. Jaworski
Primary Examiner